In the Official Action, Claims 8 and 11 were rejected under 35 U.S.C. § 112, second paragraph, for reciting the term "any other suitable material", and this objection has been overcome in that the term "any other suitable material" has been deleted.

In the Official Action, Claims 1, 3-12 were rejected under 35 U.S.C. § 103(a) as being obvious over Howard (US Pat. No. 4,335,116). Applicants now respectfully traverse this rejection for the reasons as set forth below.

The Examiner states that the *only* difference between Howard and the instant claims is that *the prior art teaches complex solutions that are made individually and may require more time in processing the formulation* and that *there is ample motivation provided by the prior art to use EDTA with a selenium solution to help maintain and restore mineral deficiencies in animals, particularly livestock.* In view of this difference, acknowledged by the Examiner, the Applicants hereby respectfully suggests to the Examiner that this difference in the method of preparation is fundamental to achieve an adequate trace mineral concentration so that a 5 to 10 milliliter injection can make a significant impact on the trace mineral status of the animal. The applicant suggests that an important aspect of the present invention is to develop a practically applicable injectable supplement and not to demonstrate a set of chemical compounds and the method is therefore an important difference in the success of the invented product and that this difference is not obvious. This difference from Howard is clearly indicated in the claims by the phrase "*in a single continuous process*".

As far as the Applicant is aware, despite the fact that Howard's patent was issued 20 years ago, no practically applicable product manufactured by the method according to Howard has been marketed anywhere. In contrast, since the priority date

of the present invention, 3 million doses have been sold in the USA. This is due to the fact that the method of Howard cannot produce a product that can improve the trace mineral status of an animal, particularly due to the low trace mineral concentration caused by the dilution due to the method used by Howard. In example 1 Howard only achieves a mineral concentration of 13.5 mg/ml whereas the method according to the present invention is currently producing products with a concentration of 85 mg/ml and a product containing 100 mg/ml is being developed. Applicant respectfully submits that the method according to the present invention is fundamentally new and unique.

Livestock producers will only inject livestock if a real benefit can be demonstrated. Furthermore, the subcutaneous injection is the preferred route to minimize tissue damage. Accordingly, the maximum amount that can be safely injected subcutaneously is 10ml per injection. Example 1 of Howard is compared the product obtained by the method of the present invention as follows in Table 1:

Table 1: Quantity of product required to supplement same minerals quantities

	Present invention (Examples 1 to 7)		Howard	
Mineral to be supplied	mg/ml	per 5ml injection	mg/ml	ml required for equivalent of present invention
Zinc	50	250	4	62
Manganese	10	50	3	16
Copper	15	75	1	75
Chromium	5	25	0.5	50
Selenium	5	25	5	5

Total concentration per ml according to present invention 85

Total concentration per ml according to Howard (Example 1) 13.5

Therefore the concentration according to the present invention is 6.3 times that of Howard.

An injection of Howard's product of between 25 and 50 ml would be needed to supply the levels of the minerals that would make a contribution to trace mineral status that can be supplied by a 5 ml injection of the product according to the present invention. The reason why the present invention is capable of producing the product with the concentrations as shown is due to the method, namely the continuous process compared to Howard's single product approach and the relative solubility's of the minerals to be supplied. In simple terms, 10ml of a liquid a may dissolve 10 mg of a mineral B and simultaneously 10 mg of a mineral C to obtain a 10 ml solution A having 10 mg of B and 10 mg of C. However, in accordance with Howard, where a separate solution of A is used to dissolve the 10 mg of C, then by combining the two solutions of A provides a 20 ml solution of A having 10 mg of B and 10 mg of C. Now we have a solution of which the amount is more than the maximum safe 10 ml for subcutaneous injection in an animal. In theory, several solutions, prepared by the method of Howard, could be injected separately, but it is obvious that costs, time and danger of tissue damage increase with the number of injections administered. In practice this will never happen.

Furthermore, Howard uses tetrasodium EDTA whereas the present invention uses EDTA acid and/or disodium EDTA. The variants used according to the present invention have a higher complexing power than tetrasodium EDTA. Namely EDTA acid

has a calcium complexing power of 335 mg/g, Disodium EDTA has a calcium complexing power of 266 mg/g, whereas tetrasodium EDTA has a calcium complexing power of only 220 mg/g.

Applicants wish to emphasize that, with the exception of selenium, it would be required to inject between 25 and 50 ml of the product of Howard to achieve the same level of supplementation as with the product of the present claim 1. Furthermore, a safe subcutaneous parenteral injection is normally accepted as at most 10 ml per injection. The method of Howard thus provides a non-practical product, whereas the method of the present claim 1 provides a practically applicable product. This probably is the reason why a viable product according to the method of Howard has not been marketed.

A further reason that a product based on the method suggested by Howard has not been marketed is that Howard uses the chloride salts of minerals with tetrasodium EDTA. This results in the formation of chlorides and especially sodium chloride in the injectable product. These products are unacceptable contaminants and could even be dangerous contaminants, which could cause harm especially at the high injection levels needed to boost trace mineral status of animals utilizing a product based on the method of Howard.

In addition, the process according to the present claims enables the manufacture of a product comprising high concentrations. This is impossible according to the method of Howard. For instance, preparing a mixture containing 25 mg/ml zinc plus 25 mg/ml manganese plus 25 mg/ml copper, would require mixing equal volumes containing 75 mg/ml each of zinc, manganese and copper, which would be impossible, because 75

mg/ml exceeds the complexing power of EDTA for any individual mineral. Thus, the product according to Howard cannot make a meaningful contribution to mineral status due to the low concentrations compared with a similar product of equivalent quantity prepared according to the present invention.

However, the Applicant, without prejudice, has combined claims 1, 3 and 4 and amends claims 8 and 11 to more clearly recite the subject matter of applicant's invention.

In summary, claims 1 and 5-13 are thus not anticipated or made obvious by the Howard patent, Applicants respectfully submit that 35 U.S.C § 103(a) rejection is in error and should be withdrawn.

In view of the foregoing, this application is in condition for immediate allowance. If the Examiner has questions about this response, please feel free to contact the undersigned by telephone.

Favorable consideration is respectfully requested.

Respectfully submitted,

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